

Amendments to the Specification:

Please update the substituted specification submitted on October 13th 2006 to reflect the following amendments:

- 1) The Descriptive Title of the Invention has been amended as follows:

A Method of Forming a Diffusion Barrier Layer for Implantable Devices

- 2) Please insert the following section before the "**BACKGROUND OF THE INVENTION**" section beginning on page 1:

CROSS REFERENCE

This is a divisional application of U.S. Serial Number 09/750,515 which was filed on December 28, 2000, and issued as U.S. Patent 6,663,662 on December 16, 2003.

- 3) Please replace the paragraph on page 22 of the substitute specification beginning with the sentence "The active ingredient also includes any substance capable of exerting a therapeutic or prophylactic effect in the practice of the invention" with the following amended paragraph:

The active ingredient also includes any substance capable of exerting a therapeutic or prophylactic effect in the practice of the present invention. The active ingredient can also be for enhancing wound healing in a vascular site and improving the structural and elastic properties of the vascular site. Examples of such active ingredients include antiproliferative substances as well as antineoplastic, antiinflammatory, antiplatelet, anticoagulant, antifibrin, antithrombin, antimitotic, antibiotic, antioxidant, and combinations thereof. A suitable

example of an antiproliferative substance includes actinomycin D, or derivatives and analogs thereof (manufactured by Sigma-Aldrich 1001 West Saint Paul Avenue, Milwaukee, WI 53233; or COSMEGEN® available from Merck). Synonyms of actinomycin D include dactinomycin, actinomycin IV, actinomycin I₁, actinomycin X₁, and actinomycin C₁. Examples of suitable antineoplastics include paclitaxel and docetaxel. Examples of suitable antiplatelets, anticoagulants, antifibrins, and antithrombins include sodium heparin, low molecular weight heparin, hirudin, argatroban, forskolin, vaprost, prostacyclin and prostacyclin analogs, dextran, D-phe-pro-arg-chloromethylketone (synthetic antithrombin), dipyridamole, glycoprotein IIb/IIIa platelet membrane receptor antagonist, recombinant hirudin, thrombin inhibitor (available from Biogen), and 7E-3B® (an antiplatelet drug from Centocore). Examples of suitable antimitotic agents include methotrexate, azathioprine, vincristine, vinblastine, fluorouracil, adriamycin, and mutamycin. Examples of suitable cytostatic or antiproliferative agents include angiopoietin (a somatostatin analog from Ibsen), angiotensin converting enzyme inhibitors such as ~~CAPTOPRIL~~®captopril (available from Squibb), ~~CILAZAPRIL~~®cilazapril (available from Hoffman-LaRoche), or ~~LISINOPRIL~~®lisinopril (available from Merck); calcium channel blockers (such as ~~N~~nifedipine), colchicine, fibroblast growth factor (FGF) antagonists, fish oil (omega 3-fatty acid), histamine antagonist, ~~LOVASTATIN~~®lovastatin (an inhibitor of HMG-CoA reductase, a cholesterol lowering drug from Merck), monoclonal antibodies (such as PDGF receptors), nitroprusside, phosphodiesterase inhibitors, prostaglandin inhibitor (available form Glazo), ~~S~~seramin (a PDGF antagonist), serotonin blockers, steroids, thioprotease inhibitors, triazolopyrimidine (a PDGF antagonist), and nitric oxide. Other therapeutic substances or agents which may be appropriate include alpha-interferon, genetically engineered epithelial cells, and dexamethasone. Exposure of the composition to the active ingredient is not

permitted to adversely alter the active ingredient's composition or characteristic.

Accordingly, the particular active ingredient is selected for mutual compatibility with the blended composition.

- 4) Please replace the footnote for Table 3 which is at the top of page 37 of the substitute specification with the following amended footnote:

* Exact temperature depends on the degree of hydrolysis which is also known as the amount of residual acetate

- 5) Please replace the second paragraph following Example 15 and beginning with the sentence "The IC₅₀ (concentration at which 50% of the cells stop proliferating) of actimomycin D . . ." with the following amended paragraph:

The IC₅₀ (concentration at which 50% of the cells stop proliferating) of actimomycin D was 10⁻⁹M as compared to 5 x 10⁻⁵M for mitomycin and 10⁻⁶M for docetaxel. Actinomycin D was the most potent agent to prevent SMC proliferation as compared to other pharmaceutical agents.

- 6) Please replace the paragraph following Example 27 with the following paragraph:

For a thermoset system, 1.67 grams of EPON® 828 (Shell) resin, bisphenol-A based epoxy resin, can be added to 98 grams of propylene glycol monomethyl ether and 0.33 grams of JEFFAMINE® T-430 (Huntsman), one of a family of polyoxyalkyleneamines that include primary amines attached to a polyether backbone of propylene oxide, ethylene oxide, or a combination of propylene oxide and ethylene oxide. After application, the stent can be baked for 2 hours at 80°C and 2 hours at 160°C.